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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,885

10/07/2005

Marc-Andre Theoleyre

7376

7371

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7590

10/06/2008

CASELLA & HESPOS
274 MADISON AVENUE
NEW YORK, NY 10016

EXAMINER

BRUNSMAN, DAVID M

ART UNIT

PAPER NUMBER

1793

MAIL DATE

DELIVERY MODE

10/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,885	Applicant(s) THEOLEYRE, MARC-ANDRE	
	Examiner David M. Brunzman	Art Unit 1793	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20050304</u> . | 6) <input type="checkbox"/> Other: ____. |

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6475390 (published as WO99/04903 on Feb.4 1999) in view of US 5851372.

The reference described a process for the production of crystalline lactose starting with an ultrafiltered whey permeate that is subject to a cation exchanges precolumn which exchanges Na⁺ and K⁺ ions for the multivalent cations in the whey. The process goes on to concentrate the exchanged product and crystallize the concentrated product to produce a mother liquor and crystallized lactose. Column 5, lines 19-34 teach that the ion exchange resin may be regenerated using a monovalent enriched fraction recovered from later in the process. The difference between US 390 and the instant claims is the provision in the instant claims to remove organic acid and multivalent anions from the liquid by exchanging them with monovalent anions. US 372 teaches a process for demineralizing whey wherein the ion exchange step may include an anion exchange resin in the Cl⁻ form to remove troublesome phosphate and sulfate anions. It would have been obvious to one of ordinary skill in the art to combine the teaching of US 372 with the process of US 390 because the secondary reference teaches it is desirable to remove phosphate and sulfate ions from the whey stream before crystallizing and that an anion exchange resin is effective to do so.

Claims 2-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 390 in view of US 372, as applied above, in further view of US 4955363.

The limitation introduced in claim 2 is that the mother liquor be subject to chromatography to produce a lactose enriched fraction and an ion enriched fraction. US 363 teaches a process for purifying and crystallizing lactose from whey including a step of subjecting the mother liquor to chromatograph to produce a lactose enriched fraction and a raffinate enriched in "salts" (ionic species). It would have been obvious to one of ordinary skill in the art to subject the mother liquor of US 390 to the chromatographic separation of US 363 because US 363 teaches the mother liquor from lactose crystallization can be separated into a lactose rich fraction that may be recovered and an ionic fraction. US 390 recognizes that recycle streams of monovalent ions are useful as regeneration brines. The preferred embodiment of the ion exchange step suggest by US 372 employs a mixture of cation and anion exchange resins such that regeneration would take place in parallel.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

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be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 7338561.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims substantially overlap.

Claim 14 of the patent recites a method for purification of ultrafiltration whey permeate comprising ions similar to instant claim 1 by treatment with cationic and anionic exchange resins in monovalent form followed by crystallization. Claims 4 and 8. Claims 10 and 19 teach chromatography to the mother liquor of the patent discloses modifying the process to regenerate the ion exchange resins. It would have been obvious to one of ordinary skill in the art to make these modifications because the dependent claims of a patent further define a narrow invention comprising a preferred embodiment thereof.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Brunsman whose telephone number is 571-272-1365. The examiner can normally be reached on M, Th, F, Sa; 7:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry Lorengo can be reached on 571-272-1233. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/David M Brunsman/
Primary Examiner, Art Unit 1793
